

APPENDIX G

FREQUENTLY ASKED QUESTIONS FOR PRA

INTRODUCTION

This section presents a few questions and answers relating to probabilistic risk assessment (PRA). The purpose of the frequently asked questions (FAQs) is to facilitate the understanding of PRA using a comparison with the traditional point estimate approach to risk assessment.

The FAQs presented here provide an overview of PRA with pointers to more detailed, and often more technical, discussions in other parts of the guidance.

(1) What is a risk assessment?

Risk assessment is a tool for organizing available information to make inferences about the potential human health or ecological effects associated with exposure to hazardous materials. The National Contingency Plan (NCP) addresses the use of a baseline risk assessment at Superfund sites to determine whether risks to human health and the environment are unacceptable. The NCP implements the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980.

Risk assessments traditionally provide single point descriptors of risk (e.g., a central tendency exposure (CTE) risk descriptor or a reasonable maximum exposure (RME) risk descriptor). As such, these types of risk assessments have been referred to as point estimate risk assessments.

In 1983, the National Research Council (NRC) described the following four steps for conducting human health risk assessments:

- **Hazard identification:** the determination of whether a particular chemical is or is not causally linked to a particular health effect.
- **Dose-response assessment:** the determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.
- **Exposure assessment:** the determination of the extent of human exposure before or after application of regulatory controls.
- **Risk characterization:** a description of the nature and often the magnitude of human risk, including attendant uncertainty (NRC, 1983).

Readers are referred to risk assessment guidance documents such as *Risk Assessment Guidance for Superfund (RAGS): Volume I. Human Health Evaluation Manual (HHEM) (Part A, Baseline Risk Assessment)* (U.S. EPA, 1989a), *Risk Assessment Guidance for Superfund: Volume II. Environmental Evaluation Manual* (U.S. EPA, 1989b), and *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (U.S. EPA, 1997a) for more information about point estimate risk assessment methods and policies.

(2) What is a probabilistic risk assessment (PRA)?

Superfund risk assessments have traditionally provided single point estimates of risk. More recently, PRAs have been developed. A PRA is a risk assessment that provides a probability distribution, rather than a point estimate, of risk. A probability distribution conveys both a range of values and a likelihood of occurrence of each value. This may allow a risk assessor to make statements about the likelihood that risks will exceed a level of concern. The probability distribution for risk often represents variability in risk estimates for a potentially exposed population. This variability may be due to variability in exposure and/or toxicity. PRA may also be used to quantify uncertainty in risk estimates. This can be useful because it allows a risk assessor to make statements about the level of confidence in the likelihood that risks will exceed a level of concern.

Probabilistic methods often use computer simulations to combine multiple probabilistic distributions in a risk equation. Monte Carlo analysis (MCA) is perhaps the most widely used probabilistic method in PRA (see Question #7).

(3) How does PRA compare with the point estimate approach?

A single point estimate of risk does not explicitly characterize associated variability or uncertainty. However, multiple point estimates of risk (e.g., CTE or RME) can begin to characterize variability in risk as they use different points on each input distribution for exposure). A PRA can characterize variability in risk by using the full distribution of variability in exposure parameters in the risk equations. Advanced PRA techniques can also quantitatively characterize uncertainty. In appropriate circumstances, results of a PRA can lead to more informed risk management decisions.

A PRA can be more resource intensive than a point estimate risk assessment. Some PRAs can require greater effort than point estimate approaches to define model inputs (i.e., select and fit probability distributions), as well as additional steps in the planning, review, and communication of the risk assessment assumptions and results (see Chapter 6 and Appendix F). A PRA does not necessarily require more data than a point estimate approach, although it does provide a framework for incorporating more of the available information into the risk assessment. When information on important exposure variables is lacking, results from a point estimate approach and a probabilistic approach will be equally uncertain.

If a decision is made to conduct a PRA, this does not replace a point estimate risk assessment. Results of point estimate approaches should still be presented along with results of probabilistic approaches in Tier 2 or Tier 3.

(4) Why should I consider using PRA?

PRA can have several advantages over the traditional point estimate approach to risk assessment. PRA can often provide a more complete characterization of risk; a quantitative description of the uncertainties in the risk estimates; more informative sensitivity analysis; the ability to make probabilistic statements about risk; the ability to know where specific risk levels are on the potential distribution of risk; an increased understanding of risks; and opportunities for improved communication and risk management decision making.

(5) When should I consider using PRA?

A PRA may be considered as early as the planning stages of a point estimate risk assessment or as late as after the completion of a point estimate risk assessment. Ideally, PRA should be considered as early as possible in the planning of risk assessment activities at a site so that sampling plans and data collection efforts may be appropriately directed. A PRA may be used when the risk management decision is not apparent and when the results of a PRA may inform the risk management decision. Often a risk management decision is not apparent when the site-specific risk estimate is close to the regulatory level of concern. The NCP discusses a generally acceptable range for cumulative excess cancer risk of 1E-06 to 1E-04 for protecting human health (U.S. EPA, 1990). Noncancer risks to human health and ecological health are generally characterized by a ratio of exposure to toxicity, called a Hazard Quotient (HQ) or Hazard Index (HI) for multiple contaminants. The point of departure for evaluating noncancer risks may vary from site to site, but a HQ of 1 may be a good starting point for risk management decisions.

PRA may also be considered when the results of the point estimate risk assessment suggest that risks are clearly above a risk level of concern, and a preliminary remediation goal (PRG) is needed. Because PRA and point estimate risk assessments use different techniques for quantifying variability and uncertainty, they may support different PRGs. If the results are dramatically different, further steps may be warranted to reevaluate the choices for input variables - both the point estimates, and the probability distributions and parameters (including truncation limits) for the 1-D MCA.

PRA will not be needed in many cases. Point risk estimates often produce results which are sufficient for making remedial decisions (e.g., sites are usually either heavily contaminated or only marginally contaminated). A tiered approach to risk assessment has been developed by Environmental Protection Agency (EPA) and is recommended for use in deciding when to move from point estimate risk assessments to PRAs of varying complexities. A workplan should be developed and submitted for review before beginning a PRA at any stage in the tiered process. As a general rule, if the potential value added by a PRA outweighs the additional resource required to conduct it, PRA may be warranted (see Chapter 2).

(6) How is the risk distribution from PRA used for decision making?

The EPA's *RAGS Volume I* (U.S. EPA, 1989a) and the NCP Preamble (U.S. EPA, 1990) state that the RME will generally be the principal basis for evaluating potential human health risks at Superfund sites. Ecological assessments also often consider an RME endpoint. The point estimate Superfund risk assessments use a combination of average and high-end input values to arrive at the RME. In PRA, risks are described by a probability distribution instead of a point estimate. To use a risk distribution for decision making, one needs to identify a percentile value that corresponds to the RME. *EPA's Guidelines for Exposure Assessment* (U.S. EPA, 1992a) states that, "the high-end risk means risks above the 90th percentile of the population distribution", and "the high-end estimator should not exceed the 99.9th percentile" due to uncertainty in specifying the upper tail of the input distributions in a Monte Carlo analysis. Similarly, the 90th to 99.9th percentiles of the risk distribution are recommended in this guidance as the RME range for decision making in PRA. Selection of a single point within the RME range generally requires consideration of the level of uncertainty in the risk distribution. The EPA recommends that the 95th percentile of the risk distribution be used as a starting point for risk management decisions in the absence of site-specific information.

(7) What is Monte Carlo Analysis (MCA)?

MCA is a numerical technique for PRA. MCA was developed in the 1940's during the beginnings of the nuclear power industry. MCA combines statistical analysis with modern computational techniques to calculate risk estimates, by randomly choosing different sets of input values each time. Each calculation is an iteration and a set of iterations is called a simulation. The output of a simulation used for risk assessment is a continuous probability distribution, which can be displayed in a graph in the form of either a probability density function (PDF) or corresponding cumulative distribution function (CDF). Both displays represent the same distribution, but are useful for conveying different information. For example, the PDF for risk is a good way for displaying relative probability using an area under the bell-shaped curve. The CDF for risk is generally S-shaped and can be especially informative for illustrating the percentile corresponding to a particular risk level of concern (e.g., 95th percentile=1E-06). Other uses of PDFs and CDFs are presented in Chapter 1, Exhibit 1-3. In 1997, EPA published a policy accepting the use of MCA to perform human health and ecological risk assessments (U.S. EPA, 1997a). This guidance focuses on MCA as a method of quantifying variability and uncertainty.

(8) What is the policy on using PRA to characterize variability or uncertainty in toxicity or dose response?

In human health risk assessments, probability distributions for risk should reflect variability or uncertainty in exposure. In ecological risk assessments, risk distributions may reflect variability or uncertainty in exposure and/or toxicity (see Chapter 1, Sections 1.4 and 1.4.1, Item 3).

Approaches to characterizing variability and uncertainty in toxicological information should reflect both the latest developments in the science of hazard and dose-response evaluation and consistent application of EPA science policy. This statement is consistent with the *1997 EPA Policy Statement* presented in Section 1.4 above (U.S. EPA, 1997g). Probabilistic approaches to ecological dose-response assessment may be explored, as discussed and demonstrated in Chapter 4. This guidance does not develop or evaluate probabilistic approaches for dose-response in human health assessment and, further, *discourages undertaking such activities on a site-by-site basis*. Such activities require contaminant-specific national consensus development and national policy development. Parties wishing to undertake such activities should contact the OERR to explore ways in which they might contribute to a national process for the contaminant of interest to them.

(9) What is the policy on using PRA at EPA and in Superfund?

In the spring of 1997, EPA released the memorandum, *Use of Probabilistic Techniques (including Monte Carlo Analysis) in Risk Assessment* (U.S. EPA, 1997b). The policy states that probabilistic analysis techniques, "given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments." As such, a PRA, "will be evaluated and utilized in a manner that is consistent with other risk assessments submitted to the Agency." Together with this Policy Statement, the Agency released a set of guiding principles for use and review of probabilistic analyses. Hence, both RAGS and Agency-wide guidance emphasize the importance of review of the scientific and technical merit of a probabilistic analysis to determine whether or not the assessment is of sufficient quality to support a remedial decision. This guidance, *RAGS Volume 3: Part A*, provides risk assessors with comprehensive guidance on when and how to conduct PRAs using MCA within the Superfund program (see Preface and Chapter 1).

(10) What are the challenges of using PRA?

Although PRA may have several advantages over the traditional point estimate approach to risk assessment, the use of PRA tends to be more resource intensive and may introduce some additional challenges to risk communication efforts. Risk communication helps build trust with the stakeholders and disseminate the risk information. In general, EPA staff and stakeholders are accustomed to a point estimate of risk and are unfamiliar with PRA and the quantitative estimates of uncertainty that PRA can support. Although, quantitative risk estimates may be more informative, they also may be more difficult to communicate and may not be well received due to stakeholder desires for certainty (Slovic, et al. 1979). Early and frequent communication with stakeholders is key in implementing PRA successfully. Often PRA requires additional data collection efforts as well as more time and resources to select and fit probability distributions.

REFERENCES FOR APPENDIX G

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